

Symptoms and Antireflux Medication Use Following Laparoscopic Nissen Fundoplication: Outcome at 1 and 4 Years

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ABSTRACT

Background: We have reported 1-year outcomes and antacid medication use in 100 patients undergoing laparoscopic Nissen fundoplication. As a follow-up study, we queried these same patients to determine whether their outcomes endured 4 years after fundoplication.

Methods: One hundred patients undergoing laparoscopic Nissen fundoplication between 1992 and 1997 were asked, at 1 to 2 years and 4 to 6 years postoperatively, to grade their symptoms on a scale of 1 (mild) to 10 (severe). Patients were also queried as to the number/cost of antacid medications used before and after fundoplication.

Results: Significant improvements were noted in symptoms of heartburn, postprandial emesis, gas/bloating, and dysphagia after fundoplication. Significant decreases in antacid medication use (97% vs 19%) and monthly costs (\$168±\$91 vs \$30±\$54) were seen following fundoplication. The number of patients on antacid medications and the monthly costs of these medications (37% and \$53±\$87, respectively) increased significantly from early to late follow-up, but were still significantly lower than those before surgery. Overall, 87% and 90% of patients were pleased with their outcome at early and late follow-up, respectively, and 93% and 92% of patients stated they would consider undergoing fundoplication again if necessary ($P=NS$).

Conclusion: Laparoscopic Nissen fundoplication results in a significant reduction in the symptoms of reflux and the use of antacid medications with a high degree of patient satisfaction. Although some patients return to antacid medications at late follow-up, they continue to have few symptoms and are pleased with their outcomes.

Key Words: GERD, Reflux, Nissen, Outcomes.

INTRODUCTION

Heartburn is one of the most common chronic disorders affecting the gastrointestinal tract.¹ Due to the spectrum and variation of symptoms, the prevalence of gastroesophageal reflux disease (GERD) is difficult to define; however, surveys have shown that heartburn and acid regurgitation are experienced by approximately 20% of the United States population at least once per week.^{1,2} GERD has been shown to significantly affect patients' quality of life³⁻⁵ and is a potential risk factor for adenocarcinoma of the esophagus.⁶⁻⁸ Traditionally, GERD has been managed initially with a combination of dietary changes, antacids, H_2 -antagonists, and more recently, proton pump inhibitors.⁹ Surgical management is generally reserved for patients with persistent symptoms on maximal medical therapy or patients with complications of GERD, such as esophageal ulcer, esophageal stricture, Barrett's esophagus, or aspiration pneumonia.¹⁰

Laparoscopic Nissen fundoplication is well established as an effective surgical therapy for the treatment of GERD, yielding substantial symptomatic improvement and reductions in the use and cost of antacid medications.¹¹⁻¹⁵ The durability of these gains, however, have recently been called into question, as failures in surgical therapy have become more apparent.¹⁶⁻²⁰

In 1996, we queried our first 100 consecutive patients who underwent laparoscopic Nissen fundoplication to determine the patients' subjective measurement of their reflux symptoms before and after fundoplication, as well as the monthly cost of medications used to treat these symptoms.¹⁵ Significant improvement in the patients' evaluation of their typical and atypical GERD symptoms was seen, as well as significant savings in monthly antacid medication costs at a mean follow-up of 9 months.

In our original study, we noted that 20% of patients continued to use antacid medications following laparoscopic Nissen fundoplication (vs 97% before surgery), though significantly fewer medications were being taken per patient (0.3 ± 0.6 vs 1.8 ± 0.9) at a significantly reduced monthly cost (\$30±\$54 vs \$170±\$91). These patients stated that their symptoms were significantly improved rela-

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tive to before fundoplication and that they were pleased with their outcomes. As a follow-up study, we queried the same 100 patients to determine whether the documented improvements in symptoms endured over time and to elucidate the pattern of antacid medication use at long-term follow-up. Our hypothesis in undertaking this study was that patients would continue to have similar and significant improvements in symptoms compared with those before fundoplication as seen at early follow-up and that antacid medication use would remain relatively constant compared with that reported in our first study.

METHODS

Preoperative Assessment

Preoperatively, all patients were evaluated with esophageal manometry and 24-hour ambulatory pH monitoring. Criteria for surgical intervention were (1) a DeMeester score greater than 14.72,²¹ (2) a good correlation between symptoms and reflux episodes, (3) continued symptoms in the face of maximum medical treatment or patient preference for fundoplication, (4) adequate esophageal motility to allow construction of a "valve" at the gastroesophageal junction, and (5) being an appropriate operative candidate.

Laparoscopic Nissen Fundoplication

Our approach to laparoscopic Nissen fundoplication has previously been described.¹⁵ Briefly, all operations were undertaken using 5 trocars. The right and left crura were exposed and the distal esophagus circumferentially dissected using a Harmonic scalpel (Ethicon Endosurgery, Cincinnati, OH). The anterior and posterior vagus nerves were identified and preserved. The gastric fundus was widely mobilized by dividing the short gastric vessels with the Harmonic scalpel. When present, the hiatal hernia was reduced and the hernia sac divided or removed. Eight centimeters of esophagus were reduced into the peritoneal cavity, and a floppy 2.5- to 3.0-cm fundoplication was undertaken over a 52 to 60 F bougie. Bougie size was determined by body habitus using a 52 to 56 F in females and 56 to 60 F in males. The wrap was tacked with 4 interrupted sutures, the first 2 of which incorporated the esophagus. The wrap was always located above the gastroesophageal junction and buttressed to the right crus to minimize tension and prevent breakdown. The esophageal hiatus was reconstructed when necessary, but

all patients had at least 1 suture placed between the left and right crura to prevent postoperative dilation of the esophageal hiatus.

Postoperative Management

Patients were started on a liquid diet on the day of the operation and advanced to a soft mechanical diet on the morning of the first postoperative day. Patients were generally discharged within 24 to 48 hours once tolerating a soft diet with instructions to advance to a regular diet at home over the ensuing week.

Follow-up and Survey

Patients were seen at the clinic within 2 weeks of the operation, then at 3, 6, and 12 months, and as needed thereafter. At each visit, patients were asked to complete a questionnaire designed to assess patient satisfaction, medication use, and symptoms. Patients who did not return for follow-up received questionnaires by mail or were contacted by telephone. Using a Likert scale that ranks symptoms numerically as least ("1") to most ("10") bothersome, patients were asked to grade a variety of symptoms related to typical and atypical GERD. The questionnaire also asked patients to list all medications and dosages, monthly antacid medication costs, and any changes in sleeping habits or diet instituted to prevent GERD symptoms. Overall satisfaction with the operative experience, including hospitalization, postoperative convalescence, and postoperative symptoms were graded as very satisfied, satisfied, indifferent, unsatisfied, or very unsatisfied. Finally, patients were asked whether or not they were pleased with their postoperative outcome. Four years after the initial survey, identical questionnaires were mailed to the entire series of patients. Those patients who did not respond to the mailed questionnaires were surveyed by telephone by an examiner blinded to the previous outcomes.

Statistical Analysis

Patient responses were entered into a database (Microsoft Excel) and statistical analysis was undertaken using True Epistat (Epistat Serviced, Richardson, TX). Data were compared using the Student *t* test, chi-square analysis, or Fisher's exact test. Significance was accepted with 95% confidence. Data are presented as mean±SD, when appropriate.

Table 1.
Demographics of Patients Undergoing Laparoscopic Nissen Fundoplication

	Early Follow-up	Late Follow-up
Age in years (range)	51 (15-77)	54 (19-79)
Sex	48 Male/52 Female	41 Male/43 Female
Mean follow-up (months)	9±8*	50±12*

*Mean±SD

RESULTS

Demographics

Between 1993 and 1997, 100 consecutive patients undergoing laparoscopic Nissen fundoplication completed questionnaires a mean 9±8 months after surgery. During the second follow-up period, 84 of the 100 patients returned questionnaires or were contacted by telephone (mean follow-up 50±12 months). These patients on average were in their sixth decade, and 51% of the patients were males (**Table 1**). Of the patients lost to follow-up, 3 died of unrelated causes and 13 were unable to be located. Ten patients had undergone previous fundoplication at the time of entry into the study. Mean time to reoperation for these patients was 22±13 months.

Complications

Twenty-nine complications occurred during the perioperative period, including 3 fundal tears, two of which were recognized and repaired intraoperatively (**Table 2**). The third fundal tear was not recognized until the postoperative period when the patient developed intraabdominal sepsis. This patient died after a prolonged hospital stay and represents the only death in the series. Atelectasis was the most common complication and did not result in significant clinical sequelae. Pneumothorax occurred rarely and was treated by aspiration with a small catheter at the time of surgery or in the recovery room. One patient was noted to have a small area of ischemia at the tip of the spleen, which was of no clinical consequence. During the follow-up period, an additional 12 complications occurred. Incisional hernias at trocar sites were the most common long-term complication and occurred in 8 (9%) patients. Failure of fundoplication occurred in 4 patients (hiatal failure in 2, fundoplication disruption in 2), all of which underwent laparo-

scopic revision a mean 23±12 months after the original fundoplication. In all, 10 patients required reoperation during follow-up (incisional herniorrhaphy 7, fundoplication revision 3, incisional herniorrhaphy plus fundoplication revision 1). Three operations were converted to "open" to improve exposure (n=2) or to repair a fundal tear (n=1).

Medication Use

Antacid medication use decreased significantly in the early follow-up period and has remained significantly decreased at long-term follow-up when compared with

Table 2.
Complications Following Laparoscopic Nissen Fundoplication

Perioperative (Total = 29)	
Complication	Number
Atelectasis	6
Esophageal spasm	4
Fundal tear	3
Pneumothorax	3
Diarrhea	3
Abdominal pain	3
Bezoar	1
Splenic demarcation	1
Atrial fibrillation	1
Pneumonia	1
Intrahepatic abscess	1
Minor GI hemorrhage	1
Hyperemesis	1
Follow-up (Total = 12)	
Incisional hernia	8
Hiatus failure	2
Wrap disruption	2

Table 3.
Antacid Medication Use and Monthly Costs to Patients Before and After Laparoscopic Nissen Fundoplication

	Preoperative	Early Follow-up	Late Follow-up
Patients taking antacid medications	97 (97%)	19 (19%)*	31 (37%)*†
PPI‡	59 (59%)	8 (8%)*	26 (31%)*†
H ₂ -antagonist‡	46 (46%)	4 (4%)*	1 (1%)*
OTC antacid‡	22 (22%)	7 (7%)*	1 (1%)*
Promotility agent	30 (30%)	8 (8%)*	3 (4%)*
Antacid medications/patient§	1.82 ± 0.9	0.3 ± 0.6*	0.4 ± 0.6*
Antacid medication costs§	\$168 ± \$91	\$30 ± \$54*	\$53 ± 87*†

* $P < 0.01$ vs preoperative.

† $P < 0.05$ vs early follow-up.

‡PPI=Proton pump inhibitor, H₂= histamine receptor type 2, OTC=over the counter.

§Data are mean ± SD.

|| Medication costs are monthly costs of antacid medications per patient.

that before surgery (**Table 3**). The use of each individual antacid medication was significantly reduced compared with that before surgery at the time of each follow-up survey. This decreased medication use remained constant during the follow-up period. At long-term follow-up, however, proton pump inhibitor use was significantly increased compared with that at early follow-up, though the use of this medication remained reduced from that at preoperative levels ($P < 0.0001$). The subgroup of patients taking medications at late follow-up used fewer medications after follow-up [1.7 medications/person preoperatively vs 1.1 medications/person at late follow-up ($P < 0.0001$)] and reported a mean savings of \$63±\$88 per person per month from their preoperative medication costs ($P < 0.01$). At late follow-up, fewer patients were using antacids or promotility agents compared with that in both early follow-up and before fundoplication. These substantial reductions in medication use resulted in a significant decrease in monthly antacid medication costs to the patients.

Diet and Sleeping Habits

Laparoscopic Nissen fundoplication significantly improved self-imposed dietary restrictions and sleeping habits of patients at early and late follow-up. Preoperatively, 56% of patients stated that coffee aggravated their symptoms. Following fundoplication, 83% of patients reported no symptoms when drinking coffee, with another 13% reporting improvement in these symptoms. This remained unchanged at long-term follow-up. Similarly,

86% of patients avoided certain foods before fundoplication for fear of exacerbating their symptoms, and 87% found it necessary to alter their sleeping habits before fundoplication to avoid symptoms (eg, place a block under the head of the bed). After surgery, only 20% of patients continued to abstain from certain foods, and 83% were able to return to their original, preferred sleeping habits. No significant changes were observed in these habits at long-term follow-up as 79% of patients did not need to alter their diet, and 80% of patients did not need to modify their sleeping habits at the time of the second survey.

Reflux Symptoms

Patients reported significant improvements in all GERD symptoms at the time of the initial survey, and these improvements were maintained at the time of the late follow-up (**Table 4**). Prior to fundoplication, the most bothersome symptom reported was heartburn, both postprandial and nocturnal. Heartburn, along with postprandial vomiting, was uncommon and the least bothersome following surgical intervention, and these gains remained constant throughout the follow-up period. Significant improvement was noted postoperatively for all symptoms except the inability to belch or vomit, which were similar to preoperative values at long-term follow-up. Initially, patients reported a significant inability to belch, but this symptom returned to baseline by late follow-up. Bloating was the most bothersome symptom reported following fundoplication although, surprisingly, it was

Table 4.
Symptom Severity as Reported by Patients*†

Symptom	Preoperative	Early Follow-up	Late Follow-up
Postprandial heartburn	8.2±2.9	1.5±1.6‡	1.5±1.5‡
Nocturnal heartburn	7.8±3.3	1.3±0.9‡	1.6±1.9‡
Postprandial nausea	5.2±4.3	1.7±2.1‡	1.7±2.0‡
Postprandial emesis	4.3±4.2	1.2±1.3‡	1.2±1.4‡
Sensation of food stuck in throat	4.9±3.9	2.4±2.6‡	2.3±2.5‡
Sensation of food stuck in chest	4.9±2.9	2.7±2.8‡	2.0±2.0‡§
Chest pain with swallowing	4.3±3.9	2.0±2.2‡	1.7±1.9‡
Difficulty swallowing	4.1±3.8	2.4±2.7‡	1.9±2.2‡
Asthma/coughing	4.1±4.0	2.0±2.2‡	2.6±3.1‡
Gas/bloating	6.1±3.8	4.9±3.7‡	3.9±3.6‡
Inability to vomit	2.4±3.1	2.9±3.5	2.8±3.4
Inability to belch	2.6±3.1	3.8±3.5‡	2.7±3.2§

*Scale is 1 (least bothersome) to 10 (most bothersome).

†Data are mean±SD.

‡ $P<0.05$ vs preoperative.

§ $P<0.05$ vs early follow-up; Scale is 1 (least bothersome) to 10 (most bothersome).

significantly improved from preoperative levels. Patients reported continued improvement in the sensation of food sticking in the chest over the course of the study as this symptom was reported to be significantly less bothersome at long-term follow-up compared with that before surgery and at early follow-up.

Patient Satisfaction

Overall, 74 (88%) respondents were satisfied or very satisfied with their operative experience at the time of late follow-up, which was equal to the 88% satisfaction rate of the initial survey (Table 5). Of the 6 (7%) patients who reported dissatisfaction with their operation at the time of late follow-up, the only complaints reported were related to operative experience, not symptoms. Overall, 87% and 90% of patients stated that they were pleased with their outcome at early and late follow-up, respectively, while 93% and 92% of patients stated they would consider undergoing the operation again under similar circumstances.

DISCUSSION

The efficacy of Nissen fundoplication in the management of patients with severe gastroesophageal reflux is well established. To many nonsurgeons, the perceived exces-

sive morbidity associated with celiotomy and fundoplication limited referrals for fundoplication to the most complex and severe cases of reflux.¹⁸ The introduction of minimally invasive techniques along with the apparent epidemic of adenocarcinoma of the distal esophagus have served to promote the application of antireflux surgery. Although laparoscopic Nissen fundoplication has rapidly gained wide acceptance, the surgical community continues to endeavor to “fine tune” the operation to optimize long-term results. In this study, we have sought to determine whether the favorable outcomes generally achieved early after laparoscopic Nissen fundoplication endure over time. To address this, we focused on patients’ perceptions of symptoms and outcomes by surveying our first 100 patients at 2 time points approximately 1 and 4 years after fundoplication.

The patients in this study were generally middle-aged without a gender bias. At the time of late follow-up, 16 patients were not available to survey. These patients were aggressively sought by all means available but were unable (or unwilling) to be found. It is difficult to predict how this attrition affects the results of the study. In our experience with other follow-up surveys, we have found that although some patients who are doing well tend not to return questionnaires or participate in surveys, a seemingly equal number of patients with suboptimal out-

Table 5.
Patient Satisfaction Following Laparoscopic Nissen Fundoplication

	Early Follow-up	Late Follow-up
Overall satisfaction		
Very satisfied	70 (70%)	59 (70%)
Satisfied	18 (18%)	15 (18%)
Indifferent	5 (5%)	4 (5%)
Dissatisfied	3 (3%)	6 (7%)
Very dissatisfied	4 (4%)	0
Are you pleased with your outcome?		
Yes	87 (87%)	76 (90%)
No	13 (13%)	8 (10%)
Would you have the operation again?		
Yes	60 (60%)	65 (77%)*
No	7 (7%)	7 (8%)
Maybe	33 (33%)	12 (15%)*

* $P < 0.05$ vs early follow-up.

comes refuse to participate as well. Any assumptions about the patients in this study lost to follow-up, therefore, would be speculative.

Complications did occur with notable frequency but were generally minor and of no long-term consequence. One death occurred. The patients in this study include our early experience with laparoscopy and reflect our progression along the "learning curve." Three fundal tears did occur, one of which resulted in death. Also, 3 patients required conversion to open procedures. Incisional hernias occurred more often than would have been expected and with an incidence slightly higher than that reported in the literature.²² This again reflects our early experience with laparoscopy, as we now routinely close the fascia at all port sites. Finally, 4 patients presented nearly 2 years after fundoplication with demonstrable evidence of operative failure. These were all revised laparoscopically with good outcomes.

Antacid medication use dropped dramatically following fundoplication and remained significantly reduced throughout the follow-up period. The incidence of medication use did not fall to zero. In the early postoperative period, the patients tended to take these medications out of habit or misinformation (ie, they did not know they were supposed to stop taking them). A notable number of patients took antacid medications for symptoms assumed by the patients or prescribing physicians to be

related to continued or recurrent reflux. In the later periods of follow-up, what is more disturbing is that with time, significantly more patients resumed antacid medication use, often at the discretion of their primary care physician without surgical consultation or objective evidence of recurrent reflux or failed fundoplication. To many patients and referring physicians, it is certainly easier to undergo a trial of proton pump inhibitors than to undergo barium esophagography, endoscopy, manometry, 24-hour ambulatory pH monitoring, or surgical consultation. Nonetheless, patients continue to realize significant monthly cost savings 4 years after fundoplication.

Improvements in patients' symptoms were common and endured. Heartburn, both postprandial and nocturnal, was by far the most problematic symptom for patients prior to fundoplication. After surgery, the severity of heartburn was significantly reduced such that it was the least problematic symptom with the exception of postprandial emesis, which was even less severe. This held true at both early and late follow-up. Significant improvements were recognized in every typical and atypical symptom category except the inability to vomit and belch, which actually worsened early on and returned to preoperative levels at late follow-up. Symptoms of bloating, gaseousness, and the inability to belch are expected outcomes that improve with time, but, to our surprise, were actually less severe after fundoplication. We have found it helpful to warn patients in advance about these

symptoms, which usually persist for 3 or 4 weeks after fundoplication until patients unlearn the aerophagia that they developed subconsciously over time to clear the distal esophagus of refluxed gastric contents. Symptoms continued to improve with time such that, at late follow-up, symptom scores remained significantly and drastically reduced compared with those before surgery.

The improvements seen in symptoms translated into general satisfaction with the operation and outcomes. An identical proportion of patients were either satisfied or very satisfied at early and late follow-up. The few patients that were very dissatisfied at early follow-up improved slightly at late follow-up but remained dissatisfied, and 1 patient was lost to follow-up. Overall, a high degree of satisfaction was seen in patients at early follow-up, which endured with time. Interestingly, although the distribution of patients satisfied/pleased with their outcomes did not significantly change with time, significantly more patients stated that they would undergo the operation again.

As laparoscopic Nissen fundoplication continues to be applied more often, its efficacy as a permanent treatment for the symptoms of GERD is becoming more evident. Difficulty remains in defining successful outcomes. Routine postoperative ambulatory pH monitoring is difficult if not impossible to acquire due to patient reluctance, particularly in the absence of symptoms. Recurrence of symptoms and development of new symptoms, on the other hand, is often quickly ascribed to recurrent reflux without objective evidence or in the face of a poor correlation with ambulatory pH studies. Finally, the empiric application and apparent benefit of antacid medications may be due to the placebo effect. These medications, however, are often taken without much benefit. This is not to downplay the surprising number of patients taking antacid medications at late follow-up but to emphasize the importance of interpreting the implications of resumption of antacid medication use. Although approximately one third of patients were taking these medications on at least a part-time basis, they reported significant improvements in symptoms and overall satisfaction with their outcomes. They take fewer medications at a lower monthly cost while returning to their normal diets and sleeping habits. In short, a patient taking 1 pill 2 to 3 times per week while eating foods without restrictions and no longer requiring blocks under the head of their beds to sleep should not be deemed a failure of fundoplication.

In conclusion, patients note that laparoscopic Nissen fundoplication is effective in reducing the life-altering symptoms of gastroesophageal reflux. While antacid medication use tends to increase with time, patients remain happy with their outcomes and would willingly undergo fundoplication again, should it be required.

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